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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/728,423 | 12/01/2000 | Michael Houghton | 1618.003 | 3252 |

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,423

Applicant(s)

HOUGHTON ET AL.

Examiner

Myron G. Hill

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/15/03. 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the Amendment filed 15 October 2003.

Claims 1- 27 are under consideration.

Information Disclosure Statement

A signed and dated copy of the IDS filed 15 October 2003 is included with this action.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 27 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant's arguments were persuasive and the rejection is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 102

The rejection of claims 1- 5, 10, 14, 15, and 17- 25 under 35 U.S.C. 102(b) as being anticipated by Ishi *et al.* (Ishi) is maintained.

Applicant argues that the virus of Ishi is not administered to the patients and that the reference does not teach all the elements of the claims in a single source.

Applicant's arguments have been fully considered and not found persuasive. The composition comprising a polynucleotide encoding an HCV E1E2 antigen of claim 1 reads on a HCV particles. The subjects had administered to them the virus as shown by the antibody responses. While it is unfortunate that accidents happen, the subjects did have a composition comprising a polynucleotide encoding HCV E1E2 administered to them. The specification does not define "administer" but in the paragraph spanning pages 14- 15 discusses nucleic acid immunization. There is nothing in that section that specifically limits the term "administer".

Therefore, Ishi anticipates the claims.

The rejection of claims 1, 3, 5, 6, 8, 10, 12, and 14- 17 under 35 U.S.C. 102(a) as being anticipated by Forns *et al.* (Forns) is maintained.

Forns discloses a polynucleotide that encodes a E2 protein with and without P7 that can be used for eliciting an immune response to HCV E2. Forns also teaches delivery by microparticle, repeating the administration of polynucleotide encoding the protein, and that the polynucleotide is in a plasmid (Figure 1, page 1995, Figure 3, Figure 4, and Table 1).

Applicant argues that Forns does not immunize with a full length E1E2 nucleic acid and does not teach each and every element of the claimed invention.

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., all antigens are full length) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The first composition of claim 1 refers to a "composition comprising a polynucleotide encoding an HCV E1E2 antigen." The second composition requires full length E2. The specification on page 9, lines 28- 30, defines antigen as a composition that can induce an immune response for example a polynucleotide encoding a polypeptide. Pages 5 and 6 define polypeptides to include fragments and not have a minimum size. The nucleic acid of Forns meets the limitation of the first composition in the claim because it is a fragment of E1E2 that comprises only residues 384- 715.

Therefore, Forns anticipates the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 3, and 5- 26 under 35 U.S.C. 103(a) as being unpatentable over Forns *et al.* (Forns) is maintained.

It is clear from the rejection above that the Forns reference that the other claims should have been included in the rejection.

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Applicant argues that Forns does not immunize with a full length E1E2 nucleic acid, does not teach each and every element of the claimed invention, and does not provide suggestions to modify Forns to obtain the claimed invention.

Applicant's arguments have been fully considered and not found persuasive.

Claims 1, 3, 5, 6, 8, 10, 12, and 14- 17 are discussed above in the immediate previous rejection. The reference does teach an antigen as recited in claim 1 as discussed above in the immediate previous rejection. Applicant's argument that the reference teaches away is not found persuasive. As applicant points out in the response (page 10, top paragraph), Forns does teach that cell surface expressed antigen gives higher Ab titers than intercellular expression. Forns does teach the method as recited in claim 1. The claim requires the method of eliciting an immune response against a certain antigen only. The fact that Forns teaches a better response was achieved with a different antigen does not negate the fact that an immune response was elicited with an antigen that meets the limitations of claim 1.

Therefore, the claims are unpatentable over Forns.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

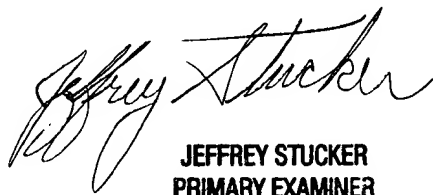
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill
Patent Examiner
January 12, 2004



JEFFREY STUCKER
PRIMARY EXAMINER